EPA

MRID NUMBER

43443200

431432-RQ

MILES

Agriculture Division

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March 1, 1994

Mr. Dennis H. Edwards, Jr.
Product Manager (19)
Registration Division (H7505C)
U.S. Environmental Protection Agency
401 M Street, SW
Washington, D.C. 20460-0001

Subject: ADMIRE 2 Flowable
EPA File Symbol No. 3125-UEE

ADMIRE 2.5 Granular
EPA File Symbol No. 3125-UEG

Pesticide and Food/Feed Additive Petitions No. 3F4169/3H5655
[Tolerance Proposal for Raw Agricultural and
Processed Commodities of Apple, Potato and Cotton]

Dear Mr. Edwards:

With regard to the subject Petitions, we have revised Section F of the tolerance proposal. In addition, we are submitting revised labels for the 2 Flowable and the 2.5 Granular in accordance with this revised section. Finally, we are also submitting several reports to address the Agency's questions concerning our analytical and residue methods.

The Section F and labels have been revised as a result of the Agency's 9/21/93 memorandum from F. Griffith to D. Edwards (contained in D. Edwards 10/5/93 letter to J. Thornton). The reports have been revised (or new data are being submitted) in response to the Agency's 6/18/93 and 9/21/93 memorandums from F. Griffith to D. Edwards.

SECTION F Revisions

We have revised Section F (attached) of the subject Petition by lowering the proposed apple and potato tolerances (RAC and FAT). The apple tolerances were lowered to the levels recommended in the Agency's 9/21/93 memorandum, as listed below:

Commodity	Previous Tolerance	New Proposed Tolerance
Apples, fruit (RAC)	1.0 ppm	0.5 ppm
Apples, pomace (wet and dry - FAT)	2.0; 7.0 ppm	3.0 ppm

The potato tolerances were lowered from the previously proposed tolerances but not to the level suggested in the Agency's 9/21/93 memorandum (listed below):

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Commodity	Previous Tolerance	Agency's Proposed Tolerance	Miles' Proposed Tolerance
Potato (RAC)	0.4 ppm	0.2 ppm	0.3 ppm
Potato, chip (FAT)	0.7 ppm	0.25 ppm	0.4 ppm
Potato, waste (FAT)	1.5 ppm	0.6 ppm	0.9 ppm

We have not lowered the potato tolerances to the levels suggested by the Agency because it is our opinion that the majority of residues are from the soil application. The foliar applications are not expected to contribute significantly to the residues detected in the potato tuber. The maximum residue level detected in the field trials was 0.28 ppm. Even though the total amount applied was 1.67X the use rate, we feel that the majority (if not all) of the 0.28 ppm was a result of the soil application. For this reason, we propose to only lower the potato RAC tolerance to 0.3 ppm, instead of 0.2 ppm (as suggested by the Agency).

ADMIRE Label Revisions

We have revised the ADMIRE 2 Flowable and the 2.5 Granular labels, in part, to address the Agency's concerns as detailed in their 9/21/93 memorandum.

In explanation, the Agency's review states:

"The petitioner has the options of either generating all new cotton field trial residue data at the proposed use, or proposing a new set of directions which accurately reflect the use pattern for generating the magnitude of the residue data, namely adding a use for treating cotton seed, and having only 2 foliar applications at a rate of 0.24 lb a.i., 7 day repeat application interval and with a 14 day PHI plus the use of the spray adjuvant Silwet L-77. For this use the petitioner needs to present additional crop field residue data from the Texas/New Mexico/Oklahoma region to improve geographical representation."

To address this concern, we are proposing a new set of use directions for cotton. We have addressed the four concerns presented in the Agency's review which are elaborated below.

First, we have submitted a use for treating cotton seed (GAUCHO 240 Flowable, 3125-UGU).

Second, our new use directions allow up to 4 foliar applications at 0.12 lb ai/a/application. The soil application amount has not changed (0.3 lb ai/a). The existing residue data reviewed in MRIDs 42556129 and 42767802 should support this use because the total of 0.5 lb ai/a per season is the same and the foliar applications in the residue trials were run at the worst case (2 applications of 0.24 lb ai/a). Concerning the foliar applications, the residue levels from 4 applications at 0.12 lb ai/a <u>should not</u> exceed the residue levels seen in the field trials conducted with 2 applications at 0.24 lb ai/a.

Third, we have characterized the type of spray adjuvant that can be used. The use directions stipulate that an "organosilicone-based spray adjuvant" may be used.

Fourth, concerning the need for additional residue data from the Texas/Oklahoma/New Mexico (TX/OK/NM), we feel that our residue data adequately represents this region. The cotton residue trials submitted to EPA included a total of 16 crop field trials conducted over 2 years. Sites were the following:

1991:		1992:	
	MS (2)		CA (2)
	CA (2)		GA (2)
	GA (2)		MS (2)
	TX (1)		TX (1)
	AR (1)		
	SC (1)		

The current production crop acreage statics for cotton (USDA Publication 1991 - Ag Statistics) are:

State	%	Number of Miles Trials
TX	31	2
CA	20	4
MS	13	4
LA	7	-
AR	7	1
AZ	6	-
TN	4	-
AL	3	-
GA	3	4
MO	2	-
OK	2	-
NC	1	-
SC	1	1
NM	1	-

The Miles' trials directly covers 73.6% of the cotton acreage. With adjacent states, our residue trials cover an additional 25% of the acreage. This totals 98.6% of the cotton acreage. Since we had 2 trials from TX (conducted in separate years) it is Miles' opinion that we <u>have</u> adequately represented the TX/OK/NM area.

In addition to the label revisions listed above, we have added the EFGWB's mandated groundwater advisory statement and the statements required by the worker protection standard.

Reports Enclosed

Miles Report 103818-1 (enclosed, an addendum to MRID 42556105) contains further identification of NTN 33893 metabolites in cotton after a seed treatment. The total amount identified in the seeds was approximately 74%, and an additional 12% was characterized.

Miles Reports 106418 and 106425 (enclosed) are independent laboratory method validations conducted with animal tissues and apple matrices, respectively.

Miles Reports 103848R-1 and 102624R-1 (enclosed) are revisions of the original animal and plant analytical methods (Miles Reports 103848R and 102624R; MRIDs 42556119 and 42556118, respectively).

Miles Reports 103833-1 and 103832-1 (enclosed) contain the additional information requested on the cattle and poultry feeding studies (relayed in the Agency's 9/21/93 memorandum). Miles Report 106247 contains answers to the analytical method questions relayed in the Agency's 6/18/93 internal memorandum.

To summarize, we are submitting a revised Section F for the apple/potato/cotton petition in which we lowered the proposed tolerances for apple and potato. We are also submitting revised ADMIRE 2 and 2.5 Granular labels to address the Agency's concerns for the cotton use directions. Two copies of the revised Section F and five copies of each of the labels are enclosed. Finally, we are submitting 8 reports which address questions contained in recent reviews from EPA's Chemistry Branch.

If there are any questions regarding this submission, please contact Karen Cain (816/242-2838).

Yours very truly,

MILES INC.
AGRICULTURE DIVISION

John S. Thornton
Manager
Registrations

Enclosures:
1) Pesticide Petition & Food/Feed Additive Petition No. 3F4169/3H5655 Section F - REVISED 2/25/94 (2 Copies)
2) ADMIRE 2 Flowable Label (EPA File Symbol No. 3125-UEE) (5 Copies)
3) ADMIRE 2.5 Granular Label (EPA File Symbol No. 3125-UEG) (5 Copies)
4) Miles Reports 103818-1, 102624R-1, 103848R-1, 106418, 106425, 103833-1, 103832-1, and 106427 (3 copies each).

TRANSMITTAL DOCUMENT

1. Name and Address of Submitter:

MILES INC.
AGRICULTURE DIVISION
P.O. Box 4913
Kansas City, MO 64120

John S. Thornton
Manager, Registrations
(816) 242-2255

2. Regulatory Action in Support of Which This Package is Submitted:

The registration of ADMIRE 2 Flowable (EPA File Symbol 3125-UEE) and ADMIRE 2.5 Granular (EPA File Symbol 3125-UEG) containing a new active ingredient - NTN 33893 for use on apples, potatoes, and cotton. Regulatory actions on this active ingredient have been assigned to Mr. Dennis H. Edwards, Jr., Product Manager 19, Registration Division.

3. Transmittal Date:

February 28, 1994

4. List of Submitted Studies:

MRID No.	Study No.	
431432Ø1	1	"Addendum 1 - Metabolism of NTN 33893 in Cotton After Seed Treatment" EPA Guideline 171-4(b), Miles Report No. 103818-1, K. Vogeler and A. Brauner, 34 pg.
431432Ø2	2	"Method for the Determination of Total Residues of Imidacloprid in Plant Materials and Beverages (Bayer Method 00200 - Reformatted)" EPA Guideline 171-4(c), Miles Report No. 102624-R1, E. Weber, 110 p.
431432Ø3	3	"Method for the Determination of Total Residues of Imidacloprid in Animal Materials (Bayer Method 0091 M001 - Reformatted)" EPA Guideline 171-4(d), Miles Report No. 103848R-1, E. Weber and U. Heukamp, 324 p.

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4 "An Independent Laboratory Method Validation for the Analysis of Imidacloprid and Metabolite Residues in Animal Tissues, Milk and Eggs Specified in Miles Report No. 103848-R" EPA Guideline 171-4, Miles Report No. 106418, M.E. Bajzik, 85 p.

43143205

5 "Independent Laboratory Validation of Miles Method No. 102624-1, Imidacloprid Related Residues in Plants, in Compliance with PR Notice 88-5" EPA ref. PR Notice 88-5, EPA Guideline 171-4, Miles Report No. 106425, T.M. Formella, 105 p.

43143206

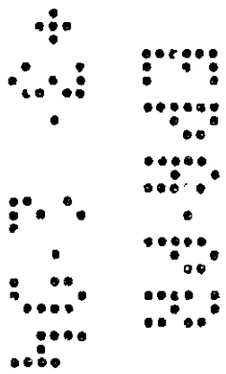
6 "NTN 33893 - Cattle Feeding Study Additional Information, Addendum 1" EPA Guideline 171-4(j), Miles Report No. 103833-1, J.J. Murphy, 8 p.

43143207

7 "NTN 33893 - Poultry Feeding Study Additional Information, Addendum 1" EPA Guideline 171-4(j), Miles Report No. 103832-1, J. J. Murphy, 7 p.

43143208

8 "Replies to Comments and Questions from the EPA Concerning the Analytical Methodology Used for Imidacloprid Residues in Crops and Animal Matrices" EPA Guideline 171-4(c,d), Miles Report No. 106427, J. J. Murphy, 18 p.



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